

Inventors: Yeaman and Shen  
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Filed: August 25, 2000  
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Rejections under 35 U.S.C. § 112, second paragraph

The rejection of claims 67-69 and 75 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, respectfully is traversed. Applicants submit that claims 67-69 and 75 are clear and definite to one possessing the ordinary level of skill in the art in view of the specification.

The Federal Circuit has had the opportunity to render a number of opinions that turned on the issue of definiteness of claim language under the second paragraph of section 112. It is clear from these decisions that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure).

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The Office Action asserts that use of the term "derivatives thereof" renders base claim 67 indefinite as it is allegedly unclear what degree of difference can exist between a parent peptide and its derivative (Current Office Action, Paper No. 19, page 3, first paragraph). Applicants respectfully submit that the term "derivative thereof" would be clear and definite to the ordinarily skilled person familiar with the teachings provided by the specification. The specification teaches, for example, at page 42 lines 12-21, that the invention peptides can be conformationally stabilized by replacing selected amino acid in the original peptide with amino acids that restrict the motion of the peptide chain, for example, beta-branched, N-methyl, alpha,beta-dehydro, alpha,alpha-dialkyl and D-amino acids. The specification also teaches that substitutions of D- or other unusual amino acids into the peptide templates can extend the half-life of an invention peptide.

In view of the teachings summarized above and other teachings provided throughout the specification, the skilled person would have understood with clarity that a derivative of an invention peptide can include molecules which contain non-amide linkages between amino acids, amino acid analogs, and other mimetics. The ordinarily skilled person having read the specification would further have known that mimetics include peptidomimetics, peptoids, or other peptide-like polymers such as poly- $\beta$ -amino acids, and also non-polymeric compounds upon which functional groups that mimic a peptide are positioned. Nevertheless, Applicants have amended base claim 67 to replace the term "derivative" with the term "mimetic," thereby rendering

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moot the rejection and defining the claimed invention with particularity.

In view of the amendments and remarks herein, Applicants respectfully submit that the pending claims are clear and definite. Accordingly, Applicants respectfully request that the Examiner remove the rejection of claims 67-69 and 75 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

#### Rejections under 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al.

Applicants respectfully submit that the above-proposed amendment to base claim 67, which deletes recitation of the phrase "derivative thereof," renders this rejection moot. Accordingly, removal of the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al. respectfully is requested.

#### CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect.

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Should the Examiner have any questions, he/she is invited to call Cathryn Campbell or the undersigned attorney.

Respectfully submitted,

May 9, 2003  
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#### Appendix A

67. An antimicrobial peptide, comprising an amino acid sequence having 13 to 74 amino acids with a 7 amino acid core sequence: aa<sub>1</sub>-aa<sub>2</sub>-aa<sub>3</sub>-aa<sub>4</sub>-aa<sub>5</sub>-aa<sub>6</sub>-aa<sub>7</sub>, wherein

aa<sub>1</sub> is the amino-terminus of the core sequence and is selected from the group consisting of alanine, lysine and glycine;

aa<sub>2</sub> is selected from the group consisting of leucine and arginine;

aa<sub>3</sub> is tyrosine;

aa<sub>4</sub> and aa<sub>5</sub> are selected from the group consisting of lysine, arginine, and histidine; and

one of aa<sub>6</sub> and aa<sub>7</sub> is selected from the group consisting of phenylalanine, tryptophan and tyrosine, such that when aa<sub>6</sub> is phenylalanine aa<sub>7</sub> is selected from the group consisting of lysine, arginine and histidine, when aa<sub>6</sub> is tryptophan aa<sub>7</sub> is lysine, and when aa<sub>7</sub> is phenylalanine aa<sub>6</sub> is leucine; and **[derivatives]** mimetics thereof that retain antimicrobial activity.